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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,840	09/19/2000	Anthony J. Kinney	BB1117 US NA	4919

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E I DU PONT DE NEMOURS AND COMPANY
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4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/664,840

Applicant(s)

CAHOON ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37,39-44 and 46-52 is/are rejected.
- 7) ☐ Claim(s) 38 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

The drawings filed February 10, 2003 have been entered.

The amendment and election filed August 22, 2002 have been entered.

Claims 1-34 have been cancelled.

Claims 35-52 are newly submitted.

5 Applicant's election of Group I in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, in view of the cancellation of the previously pending claims and the submission of new claims, all pending claims are drawn to the elected invention and are examined in this office action.

10 Claims 35-52 are pending and are examined on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 Claims 35-37, 39-44 and 46-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 2 or at least 80% identity thereto. The specification asserts that the polypeptide has delta-5 acyl-CoA desaturase activity. However, the specification does not set forth what structural or physical features of this

sequence result in the claimed activity. Therefore, the specification does not adequately describe the genus claimed.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir.

1997), where it states:

5 “The name cDNA is not in itself a written description of that
DNA; it conveys no distinguishing information concerning its
identity. While the example provides a process for obtaining
human insulin-encoding cDNA, there is no further information in
10 the patent pertaining to that cDNA’s relevant structural or
physical characteristics; in other words, it thus does not describe
human insulin cDNA . . . Accordingly, the specification does not
provide a written description of the invention . . .”

15 Therefore, given the lack of written description in the specification with regard to the
structural and physical characteristics of the claimed compositions, one skilled in the art would
not have been in possession of the genus claimed at the time this application was filed.

20 Claims are rejected under 35 U.S.C. 112, first paragraph, because the specification,
while being enabling for SEQ ID NO: 1 encoding SEQ ID NO: 2, does not reasonably provide
enablement for any nucleic acid sequence encoding a polypeptide having 80% identity to SEQ
ID NO: 2. The specification does not enable any person skilled in the art to which it pertains,
or with which it is most nearly connected, to make and/or use the invention commensurate in
scope with these claims.

25 The specification only discloses SEQ ID NO: 1 encoding SEQ ID NO: 2 having delta-5
acyl-CoA desaturase activity. However, Sequence homology is not sufficient to predict
function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June

1998), where it states that computer analysis of genome sequences is flawed, and
“overpredictions are common because the highest scoring database protein does not necessarily
share the same or even similar functions” (the last sentence of the first paragraph of page 248).
Doerks also teaches homologs that did not have the same catalytic activity because active site
5 residues were not conserved (page 248, the first sentence of the last paragraph). In addition,
Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that “there are
numerous cases in which proteins of very different functions are homologous” (page 1222, the
first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses
the problem of inferring function from homology, stating that “most homologs must have
10 different molecular and cellular functions” (see the second full paragraph of the second column
of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches
numerous problems with the sequence databases that can result in the misinterpretation of
sequence data.

More specifically, identification of related sequences that will encode enzymes having
15 a particular activity is particularly problematic in the enzymes involved in modifying fatty
acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van
de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to
other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase
(see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids
20 will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if
sequences are identified only by similarity to other sequences that are known to encode delta-5

acyl-CoA desaturase activity, one cannot conclude that these other sequences also encode enzymes having delta-5 acyl-CoA desaturase activity activity. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the
5 columns on page 225N, for example), and that "on many occasions desired goals have been impossible to achieve" (see the last paragraph on page 228N). Therefore, both the identification of other genes encoding delta-5 acyl-CoA desaturase activity activity, and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

10 Thus, given the unpredictability of identifying sequences that exhibit delta-5 acyl-CoA desaturase activity activity and modifying the lipid composition of a plant leaf; the lack of guidance in the specification for identifying and characterizing any other sequences that exhibit delta-5 acyl-CoA desaturase activity activity; the lack of working examples of delta-5 acyl-CoA desaturase activity coding sequences, and the lack of working examples of other sequences that
15 encode proteins having the same activity; and the breadth of the claims, and use of said genes or portions of said genes to modify a fatty acid; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

The claims are deemed free of the prior art as the prior art does not teach or suggest the
20 polynucleotide of SEQ ID NO: 1 or a polynucleotide that encodes SEQ ID NO: 2 or a sequence at least 80% identical thereto.

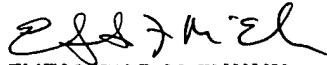
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
May 5, 2003


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600